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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

RECOR MEDICAL, INC., Plaintiff and Counterclaim-Defendant, vs. MEDTRONIC IRELAND MANUFACTURING UNLIMITED CO., Defendant and Counterclaim-Plaintiff, MEDTRONIC VASCULAR, INC., and MEDTRONIC, INC. Defendants.	Case No. 3:22-cv-03072-TLT **MEDTRONIC'S OPENING CLAIM CONSTRUCTION BRIEF** Date: October 7, 2024 Time: 11:00 a.m. Location: Courtroom 9 Judge: Hon. Trina L. Thompson

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Statutes

TABLE OF ABBREVIATIONS

Abbreviation	Meaning
'629 patent	U.S. Patent No. 8,845,629
'085 patent	U.S. Patent No. 11,801,085
Medtronic	Defendant and Counterclaim-Plaintiff Medtronic Ireland Manufacturing Unlimited Co., and Defendants Medtronic Vascular, Inc., and Medtronic, Inc. (the patentee)
Recor	Plaintiff and Counterclaim-Defendant Recor Medical, Inc. (the alleged infringer)
POSA	Person of ordinary skill in the art
Aklog Tr.	Transcript of the deposition of Recor's claim construction expert, Dr. Lishan Aklog
van der Weide Tr.	Transcript of the deposition of Medtronic's claim construction expert, Dr. Daniel van der Weide
Aklog Rpt.	Expert report by Recor's claim construction expert, Dr. Lishan Aklog
van der Weide Rpt.	Expert report by Medtronic's claim construction expert, Dr. Daniel van der Weide
IPR	*Inter partes* review

I. INTRODUCTION

The claims of Medtronic's two asserted patents clearly and distinctly set forth the claimed invention. Nevertheless, Recor proposes that ten claim terms require construction. Without exception, each of these terms has a customary meaning understood by one of ordinary skill in the art. Yet Recor still seeks to construe them, each in a way that would narrow the claim scope to try to avoid infringement—it is no coincidence that Recor's proposed constructions align squarely with its noninfringement positions. For six of the terms, Recor's proposed construction inserts a limitation not found in the claim, and far narrower than taught by the specification. For the remaining four terms, Recor misuses a statute with very specific and limited applicability—35 U.S.C. § 112(6)—to try to limit the claims to only certain embodiments. Each of Recor's positions violates fundamental tenets of claim construction law and should be rejected.

A term's plain and ordinary meaning is the default in claim construction, and therefore there is a "heavy presumption in favor of the ordinary meaning." *Prima Tek, II, L.L.C. v. Polypap S.A.R.L.*, 318 F.3d 1143, 1148 (Fed. Cir. 2003). Only if the patentee provides a special definition, or clearly and unambiguously disclaims the ordinary meaning, is a different construction appropriate. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 690 F.3d 1318, 1324 (Fed. Cir. 2012) (citing *Phillips v. AWH Corp*., 415 F.3d 1303, 1316 (Fed. Cir. 2005)). Here, because the plain and ordinary meaning of the disputed terms is consistent with the intrinsic and extrinsic evidence, and there is no disclaimer of claim scope, there is no basis for the narrowing constructions that Recor proposes. The Court should adopt Medtronic's proposals and construe the terms according to their plain and ordinary meaning.

II. RELEVANT LEGAL STANDARDS

A. Claim construction generally

The words of a patent claim are generally given their "ordinary and customary meaning," which is the meaning that would have been understood by one of skill in the art in view of the language of the claims, the specification (including the drawings), and the prosecution history of

the patent, including the cited references. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-17 (Fed. Cir. 2005) (*en banc*).

Claim construction "begins with the words of the claim," and the Federal Circuit has recognized that there is a "*heavy presumption* in favor of [using] the ordinary meaning." *Prima Tek, II, L.L.C. v. Polypap S.A.R.L.*, 318 F.3d 1143, 1148 (Fed. Cir. 2003) (emphasis added). That a claim term is disputed does not mean that it necessarily must be construed by the Court. Indeed, when a claim term has an ordinary meaning—i.e., would have been understood by one of skill in the art—then the term need not be construed. *See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1325-26 (Fed. Cir. 2012) ("The district court did not err in concluding that these terms have plain meanings that do not require additional construction.").

If, however, construction is found to be appropriate, then the specification is "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). For example, "the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* The embodiments of the invention described in the specification may also inform the construction of claim terms. For example, the claims should not be interpreted "in a way that would omit a disclosed embodiment absent clear evidence to the contrary." *Apple Inc. v. Corephotonics, Ltd.*, 81 F.4th 1353, 1359 (Fed. Cir. 2023). But, "[g]enerally, particular limitations or embodiments appearing in the specification will not be read into the claims." *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998) (quoting *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 867 (Fed. Cir. 1985)).

The prosecution history may also be relevant in construing claim terms. *Phillips* at 1317. For example, it may demonstrate "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* "The doctrine of prosecution disclaimer 'preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.'" *Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1374 (Fed. Cir. 2022) (quoting *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003)).

"Prosecution disclaimer can arise from both claim amendments and arguments made to the PTO." *Tech. Properties Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1357 (Fed. Cir. 2017).

However, prosecution history disclaimer "does not apply unless the disclaimer is 'both clear and unmistakable to one of ordinary skill in the art.'" *Tech. Properties Ltd.*, 849 F.3d at 1357 (quoting *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007)). "If the challenged statements are ambiguous or amenable to multiple reasonable interpretations, prosecution disclaimer is not established." *Genuine Enabling Tech.*, 29 F.4th at 1374 (citing *Tech. Properties Ltd.*, 849 F.3d at 1358).

Finally, courts may also consider "extrinsic evidence"—including expert opinions, dictionaries, treatises, and testimony—in construing patent claims, although it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (citation omitted).

B. Indefiniteness

A claim is indefinite, and therefore invalid, only if it fails to inform, with "reasonable certainty," those skilled in the art about the scope of the invention when read in light of the patent's specification and prosecution history. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). Definiteness is to be assessed from the viewpoint of a person skilled in the art at the time the patent was filed. *Id.* at 908. Moreover, "a claim is not indefinite just because it is broad" or lacks "mathematical precision." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1347 (Fed. Cir. 2022). The party asserting indefiniteness "ha[s] the burden of proving [it] by clear and convincing evidence." *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

C. Means-plus-function claims

35 U.S.C. § 112(6) applies to "means-plus-function" claim terms. "A means-plus-function limitation recites a function to be performed rather than definite structure or materials for performing that function …." The first step in determining whether § 112(6) should apply is to determine whether the claim term is in fact a means-plus-function term. If so, the Court looks to the "corresponding structure" for performing the function in the specification, and limits the

claim to that particular structure and equivalents thereof. *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1318 (Fed. Cir. 2003).

"[A]lthough the specification often describes very specific embodiments of the invention," it is a fundamental principal of claim construction that limitations should not be imported from the specification to "confin[e] the claims to those embodiments." *Phillips*, 415 F.3d at 1323. Section 112(6) is a limited exception to this rule, and applies when the claim uses very specific means-plus-function language. *Dolby Labs., Inc. v. Lucent Techs. Inc.*, No. C-01-20709 JF (RS), 2003 WL 25784512, at *2 (N.D. Cal. Nov. 18, 2003).

"[P]recedent has long recognized the importance of the presence or absence of the word 'means,'" and "[t]he failure to use the word 'means' creates a rebuttable presumption that [§ 112(6)] does not apply." *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1007 (Fed. Cir. 2018) (citations omitted). In the absence of the word "means," the presumption against § 112(6) can be rebutted only "if the challenger *demonstrates* that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Id.* (citations omitted, emphasis in original). This presumption is not met where the claim term has a reasonably well understood meaning in the art. *Dyfan, LLC v. Target Corp.*, 28 F.4th 1360, 1365 (Fed. Cir. 2022) (citations omitted).

If the presumption is overcome, then the question asked is "[w]hat, if any, is the structure corresponding to the function?" *Dyfan*, 28 F.4th at 1366. "Structure disclosed in the specification qualifies as 'corresponding structure' if the intrinsic evidence clearly links or associates that structure to the function recited in the claim." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1352 (Fed. Cir. 2015). The claim is limited to that "corresponding structure" and its equivalents, or, "[i]f the patentee fails to disclose adequate corresponding structure, the claim is indefinite." *Id.* at 1351-52. For a claim containing a means-plus-function limitation to be found indefinite for lacking structural support, there must be "clear and convincing evidence that the specification lacks disclosure of structure sufficient … to perform the recited function." *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376-77 (Fed. Cir. 2001).

III. PERSON OF ORDINARY SKILL IN THE ART

A POSA of the asserted patents is a person, or combination of persons, having a medical degree or equivalent in a discipline relevant to the claimed invention, specific knowledge of the circulatory and nervous system in relation to the kidneys, and/or a bachelor's or master's degree in chemical, mechanical, electrical, or biomedical engineering with at least five years practical experience in designing and developing medical devices.

IV. THE PATENTS-IN-SUIT

Medtronic asserts two patents in this case: U.S. Patent Nos. 8,845,629 and 11,801,085. (Exs. A and B)[1]. Both patents relate to systems and methods for renal denervation—the process of damaging the nerves surrounding the renal arteries—to treat hypertension.[2]

The '629 patent claims "[a]n ultrasound apparatus" for thermally-induced renal neuromodulation." (Ex. A at 16:5-6.) The apparatus includes an "ultrasound transducer" within an "expandable member" that is carried by a catheter for delivery within a blood vessel. (*Id*. at 16:7-20.) As explained in the specification, an objective of the '629 patent is to address the need "to protect smooth muscle cells or other non-target tissue from thermal damage during the thermally induced renal neuromodulation." (*Id.* at 5:6-10.) Accordingly, the claimed apparatus "transmit[s] ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury." (*Id*. at 16:7-20.) The specification explains that this "protecting" can be achieved by convective cooling elements, utilizing blood flow as a heat sink, or injecting thermal fluid, for example. (*Id*. at 5:6-17, 9:9-12.)

Like the '629 patent, the '085 patent claims a system, as well as a method, for renal neuromodulation. (*See* Ex. B at 33:49-35:32.) By contrast, however, the '085 patent is not limited to ultrasound energy. Instead of an ultrasound transducer, the '085 patent claims a "neuromodulation element" through which different types of "energy" can be delivered. (*Id*. at

[1] All exhibits referred to herein are attached to the accompanying Declaration of Keeley I. Vega.

[2] Denervation, neuromodulation, and ablation all refer to this same concept of altering nerve activity.

33:53-59, 34:45-59.) The specification explains that the energy can include "electromagnetic energy, radiofrequency, ultrasound (including high-intensity focused ultrasound), microwave, light energy (including laser, infrared and near-infrared) etc." (*Id*. at 4:49-56.) The '085 patent also claims "a generator" that "deliver[s] the energy, via the least on neuromodulation element, to the neural fibers to reduce sympathetic nerve activity in the neural fibers."

V. EVALUATION OF DISPUTED TERMS IN THE '629 PATENT

A. "an ultrasound transducer carried by the catheter, wherein the ultrasound transducer is configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury" (Claim 1)

Medtronic's Proposed Construction	Recor's Proposed Construction
"an ultrasound transducer carried by the catheter, wherein the ultrasound transducer is configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while non-target tissue in the blood vessel wall is protected from thermal injury."	"ultrasound transducer" must be configured to both: (a) "transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel wall to thermally induce modulation of target renal neural fibers"; and (b) "protect[] non-target tissue in the blood vessel wall from thermal injury" at the same time.

While the proposed term for construction is lengthy,[3] the parties' real dispute is whether the protection of non-target tissue must be performed by the claimed "ultrasound transducer," or whether other components of the system (alone or in combination with the ultrasound transducer) may perform the protecting function. A POSA reading the claim, particularly in view of the specification, would understand that the protection can be accomplished in a variety of ways, not just via the ultrasound transducer, consistent with the ordinary mean of the claim.

Claim 1 of the '629 patent recites "an ultrasound transducer carried by the catheter, wherein the ultrasound transducer is configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury." This

[3] Recor proposed the construction of this phrase and, separately, three terms that appear within this phrase: "protecting non-target tissue in the blood vessel wall from thermal injury," "blood vessel wall" and "thermal injury," which are addressed below in separate sections.

phrase goes to the heart of Medtronic's invention: modulating target nerve fibers while the non-target tissue is protected from injury. The language of the claim is clear that it is the ultrasound transducer that transmits ultrasound energy waves to the target nerve fibers. It is also clear that this happens while non-target tissue is protected from thermal injury.

There is nothing in the claim or intrinsic or extrinsic evidence that requires the protection to be carried out by the ultrasound transducer. Rather, the claim language itself expressly describes that the role of the "ultrasound transducer" is to transmit ultrasound energy waves, as stated in the claim language: "*the ultrasound transducer is configured to transmit ultrasound energy waves*." (Ex. A at 9-14.) The claim does *not* say "the ultrasound transducer is configured to protect non-target tissue." ReCor's proposed construction ignores the patentee's word choices and the grammatical difference between "to target renal neural fibers" and "while protecting," which allows that some structure other than the transducer may be responsible for performing the protecting function.

This is consistent with the specification, which teaches various mechanisms—in addition to and/or apart from the "ultrasound transducer"—that can protect non-target tissue. For example, "protective cooling elements, such as convective cooling elements, optionally may be utilized to protect smooth muscle cells or other non-target tissue." (Ex. A at 5:6-8.) Further, "the non-target tissue may be protected by utilizing blood flow as a conductive and/or convective heat sink that carries away excess thermal energy (hot or cold)." (*Id.* at 5:14-17.) Even more, "thermal fluid [] may be injected into the vessel to remove excess thermal energy and protect the non-target tissues." (*Id.* at 9:9-12.) In view of these descriptions, the claim should not be construed as limited to embodiments in which only an ultrasound transducer performs the protection, as Recor proposes. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) ("It is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.") (alteration and citations omitted).

B. "protecting non-target tissue in the blood vessel wall from thermal injury" (Claim 1)

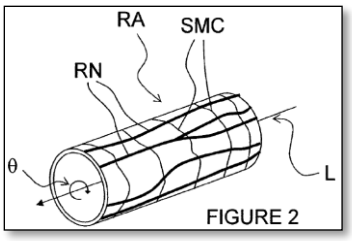
Medtronic's Proposed Construction	Recor's Proposed Construction
"non-target tissue in the blood vessel wall is protected from thermal injury."	"protecting non-target tissue in the blood vessel wall from thermal injury" is not met if adventitia is ablated.

The claims of the '629 patent cover the modulation (or ablation) of target nerves while non-target tissue in the blood vessel wall is protected. Recor contends non-target tissue is not protected if the outer layer of the blood vessel wall, the adventitia, is ablated.[4] In other words, Recor suggests that "protection" is only achieved if there is absolutely no injury to any portion of the blood vessel wall. There is nothing in the '629 patent itself or the intrinsic record that supports this limiting caveat, and it conflicts with basic renal anatomy.

The '629 patent makes clear that protecting from thermal injury is different than avoiding ablation. (Ex. C (van der Weide Rpt.) at ¶ 56.) Throughout the specification, the protection of non-target tissue from injury is described as a reduction of risk, rather than a complete lack of ablation. For example, it provides that "[i]n some embodiments, protective elements may be provided *to reduce a degree of thermal damage* induced in the non-target tissues." (Ex. A at Abstract (emphasis added).) Similarly, it teaches that a positioning element "*may reduce a risk* of *injury* to non-target," (*id.* at 7:40-42 (emphasis added)), a heat sink can "reduce[] risk of damage to the non-target tissue" (*id.* at 8:62-64), and "[a] the thermoelectric element may be insulated to reduce a risk of thermal damage to the non-target tissues" (*id.* at 7:40-42). (*See also* Ex. C (van der Weide Rpt.) at ¶¶ 55-57).) That the patent describes the avoidance of damage in terms of degree or risk, and not complete elimination, directly undermines Recor's proposal. If "protecting" *cannot* mean decreasing the *degree or risk of damage*, then these teachings would be meaningless. The Court should not adopt a construction that directly conflicts with the '629 patent's specification. *See Puma Biotech., Inc. v. AstraZeneca Pharms. LP*, No. 21-cv-1338-MFK, 2023 WL 2683559, at *6 (D. Del. Mar. 29, 2023) (rejecting a "construction [that] would render [an] [e]mbodiment meaningless").

[4] In the context of the '085 patent, the parties have agreed that "ablate renal neural fibers" means "irreversibly damage renal neural fibers."

Moreover, a construction of the claim that would preclude any ablation of the adventitia—as Recor proposes—would conflict with the anatomy of the renal vasculature, rendering the claim nonsensical. As the '629 patent describes and depicts, "the renal anatomy also includes renal nerves RN extending longitudinally along the lengthwise dimension L of renal artery RA, *generally within the adventitia of the artery*," as shown in Figure 2:



(Ex. A at 5:50-54 (emphasis added), FIG. 2.) More specifically, as Recor's expert acknowledged, renal nerves can reside outside *and within* the adventitia of the blood vessel wall. (Ex. D (Aklog Tr.) at 19:15-22.) Medtronic's expert further explained that "because renal nerves—as a matter of indisputable physiology—can run in the tissue of the adventitia, and it is difficult to discriminate between the two, ablation of the renal nerves can cause damage to adjacent areas of the adventitia." (Ex. C. (van der Weide Rpt.) at ¶ 58.) Thus, a POSA having this fundamental knowledge would not understand the patent, the claim, or this term to require complete prevention of thermal injury at the adventitia as it would undermine the entire purpose of the invention. They would instead recognize that non-target tissue can be protected even if adventitia is ablated to some degree. The Court should therefore reject Recor's limiting proposal and construe "protecting non-target tissue in the blood vessel wall from thermal injury" as "non-target tissue in the blood vessel wall is protected from thermal injury."

Medtronic anticipates Recor will argue that its construction is supported by prosecution history disclaimer, and specifically Medtronic's positions taken in the IPR proceedings that confirmed the validity of the '629 patent. But Medtronic's position here is entirely consistent with its discussion of this term during the IPR: Medtronic discussed an ablation system lacking a mechanism for protecting blood vessel tissue in the context of U.S. Patent No. 6,669,655 ("Acker"). Acker disclosed "[a] sonic emitting element . . . for treating tissue in the body." (Ex. E (Acker) at 1:13-15.) Critically, Acker is not an instrument for ablating *renal* nerves but is,

instead, explicitly designed for the "ablation of *blood vessel walls*." (*Id*. at 8:24-25 (emphasis added).) As Medtronic pointed out in the IPR, applying Acker to "target renal nerves" meant "ignoring all of the other things that will be ablated in its path." (Ex. F (IPR Paper 31) at 42:14-17.) Medtronic stated that adventitia was not protected when it was ablated *in this specific context*. Medtronic did not, however, take the position that ablation of the adventitia would be the same as not protecting non-target tissue in the blood vessel wall from thermal injury, which is what Recor would have to show here for prosecution history disclaimer to apply. *See, e.g.*, *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1120 (Fed. Cir. 2016) ("In the context of the overall prosecution history, the isolated statements plucked from [the record] do not meet the high standard for prosecution disclaimer to attach.").

C. "blood vessel wall" (Claim 1)

Medtronic's Proposed Construction	Recor's Proposed Construction
Plain and ordinary meaning / no construction necessary.	The intima, media, and adventitia of the blood vessel.

There is no dispute that, as a matter of basic physiology, a blood vessel wall is composed of three layers: the intima (inner layer), media (middle layer), and adventitia (outer layer). (*See* Ex. C (van der Weide Rpt.) at ¶ 66; Ex. G (Aklog Rpt.) at ¶ 58.) The dispute is whether the term should be construed to read in these anatomical terms in place of the words "blood vessel wall." Medtronic believes the straight-forward term "blood vessel wall"—which both parties' experts agree should be given its plain and ordinary meaning[5]—does not require construction, and that Recor's proposed construction would be unhelpful to the jury and is improperly narrow.

Were the Court to adopt Recor's construction, it would mean that any use of "blood vessel wall" would necessarily refer to all three layers. Even Recor's own expert admits that cannot be correct, as in certain contexts "blood vessel wall" can refer to less than all three

[5] *See* Ex. C (van der Weide Rpt.) at ¶ 63 ("[blood vessel wall] carries its plain and ordinary meaning"); Ex. G (Aklog Rpt.) at ¶ 56 ("a POSA would have understood 'blood vessel wall' in the '629 patent consistent with its plain and ordinary meaning").)

layers. (Ex. D (Aklog Tr.) at 60:7-61:17.)[6] In fact, the '629 patent discusses the vessel wall in ways that would *not* be understood as requiring all three layers of the wall. For example, it describes intravascular "wall-contacting electrodes" that "contact the vessel wall," which Recor's expert acknowledged excluded the media and adventitia layers. (Ex. A at 9:34-48; Ex. D (Aklog Tr.) at 52:17-53:5.) Thus, an interpretation of the vessel wall as requiring all three layers would be inconsistent with this use in the specification, as the electrode is in contact with only the intima layer.

For these reasons, a POSA would interpret "blood vessel wall" according to its plain and ordinary meaning, not narrowly as Recor requests, and the Court should do the same.

D. "thermal injury" (Claim 1)

Medtronic's Proposed Construction	Recor's Proposed Construction
Plain and ordinary meaning / no construction necessary.	Damage as a result of raising the temperature above about 37 degrees Celsius. Alternatively: indefinite

The parties dispute whether the claim term "thermal injury" is understood by a POSA as including any thermal injury, or whether it should be limited to only a very specific type of injury, as Recor proposes.

A POSA—someone who the parties agree would have advanced medical or engineering training and expertise—would readily understand the meaning of the term "thermal injury" as a class of injuries, ranging from minor thermal damage to complete tissue destruction. (*See* Ex. C (van der Weide Rpt.) at ¶¶ 70-71.) The claims and the specification use the term consistent with this ordinary meaning, explaining that it includes different types of injuries, such as "non-ablative thermal injury" or "ablative thermal injury" (both caused by heating) and "non-freezing thermal injury" or "freezing injury" (both caused by cooling). (*See, e.g.*, '629 patent at 4:13-

[6] Oddly, although Recor's expert endorses Recor's proposed construction, he has no opinion on whether "blood vessel wall" as used in the claim refers to all three layers. (*Id.* at 64:21-25 ("Q. And as it's used in claim 1, blood vessel wall, would a person of ordinary skill understand that term in the context of that claim to mean all three layers? A. I haven't formed an opinion on that.").)

32.) For this reason, the Court should assign "thermal injury" its plain and ordinary meaning, without imposing a special or narrowing construction.

Recor argues, by contrast, that the '629 patent does not use "thermal injury" according to its ordinary meaning and instead provides a special meaning—"damage as a result of raising the temperature above about 37 degrees Celsius." Nothing in the '629 patent, however, warrants limiting the scope of "thermal injury" in such a way and, in fact, doing so would improperly exclude explicit embodiments in the '629 patent. The patent explains that "thermal injury" can be accomplished through *either* heating or cooling, each with its own sub-types of injury. For example, "[t]hermal heating mechanisms" can "achieve non-ablative thermal injury[] or . . . ablative thermal injury." (Ex. A at 4:16-21.) Likewise, "[t]hermal cooling mechanisms" can achieve "non-freezing thermal injury" or "freezing thermal injury." (*Id.* at 4:25-32.) As such, restricting "thermal injury" to *just* heating reads out embodiments featuring freezing. This is improper because "where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment." *See GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1311 (Fed. Cir. 2014) (citations omitted).

Recor's only apparent support for this proposed construction is its expert's unsupported opinion that the plain and ordinary meaning of "thermal injury" to a POSA would be ablative injury only. (Ex. G (Aklog Rpt.) at ¶ 72.) However, during deposition, Dr. Aklog admitted that tissue injury during renal denervation is not limited to irreversible injury and can also include reversible injury. (Ex. D (Aklog Tr.) at 80:5-19 ("In the process of doing so, is it possible that other cells in the vicinity could be exposed to temperatures, or temperatures or temperature and durations that were insufficient to lead to cell death, and irreversible injury? Sure.").[7] Dr. Aklog's current opinion also conflicts with his own patent that describes cellular injury as including both reversible/non-ablative injury *and* irreversible/ablative injury. (Ex. H (Aklog Depo. Ex. 4) at 2:5-9.) And his current opinion is further undermined by Recor's own extrinsic evidence, which describes thermal injury in terms of degree and not as limited to complete

[7] Both parties use the terms "ablative injury" and "irreversible injury" synonymously.

tissue destruction. (Ex. I (Aklog Depo. Ex. 5) at 1 (describing "the temperature and the time required to produce a specific degree of thermal injury.").

The '629 patent makes clear that "thermal injury" is used consistent with its ordinary meaning, which would be readily understood by a POSA as any type of thermal injury, not just one specific type. Accordingly, no express construction is required and the Court should decline Recor's invitation to unnecessarily limit the term to only a specific type of injury.

E. "expandable member" (Claim 1)

Medtronic's Proposed Construction	Recor's Proposed Construction
Plain and ordinary meaning / no construction necessary.	Means-plus-function under 35 U.S.C. § 112 ¶ 6 (pre-AIA). **Functions**: (1) "vary between a reduced configuration for delivery and retrieval and an expanded deployed configuration," and (2) surround the ultrasound transducer. **Structure**: a balloon or an expandable wire basket or cage.

The term "expandable member" does not require construction because a POSA would readily understand the scope and structure of this term in the context of the patent and claims. Nevertheless, Recor proposes that the Court apply § 112(6), which governs mean plus function claims, to limit the term to "a balloon or an expandable wire basket or cage." Recor's argument ignores the presumption against applying § 112(6), the structural limitations imposed by the rest of the claims, and the background knowledge a POSA would use when reading the patent.

First, "expandable member" is not a functional limitation. That the member is expandable is a characteristic or quality, not a function. For that reason alone, § 112(6) does not apply. Additionally, because the "expandable member" term lacks the word "means," there is a presumption that § 112(6) does not apply. *Dyfan*, F.4th at 1370. The term's use of the word "member" does not affect this presumption, and courts routinely construe terms that recite "member" as not limited by § 112(6). *See, e.g.*, *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1023-24 (Fed. Cir. 2006) (construing "compression member" as not § 112(6)); *Asetek Danmark A/S v. CoolIT Sys. Inc.*, No. 19-cv-00410-EMC, 2020 WL 4207520, at *11 (N.D. Cal. July 22, 2020) (construing "intermediate member" as not § 112(6)).

Accordingly, Recor bears the burden of rebutting this presumption by showing that the claim term "fails to recite sufficiently definite structure." *Dyfan*, F.4th at 1370.

Recor cannot rebut this presumption because this term, in the context of the '629 patent, has sufficiently definite structure. Specifically, Claim 1 specifies that the "expandable member" is "carried by a distal region of the catheter," is "configured to vary between a reduced configuration for delivery and retrieval and an expanded deployed configuration," and is able to have an "ultrasound transducer [] positioned on a shaft of the catheter and within the expandable member." (Ex. A at 16:9-20.) A POSA would recognize these are physical characteristics that provide further structure to "expandable member." (*See* Ex. C (van der Weide Rpt.) at ¶ 76 ("In the view of this context . . . a [POSA] would readily appreciate the structure and configuration of the 'expandable element' . . . .").) This defined structure provides more than sufficient information about the configuration of the "expandable member" such that a limiting construction is not warranted.

Recor's expert's testimony to the contrary should be given little weight. Dr. Aklog himself uses the term "expandable member" in his own patents, recognizing that it is a known element to a POSA. (*See, e.g.*, Ex. J (Aklog Depo. Ex. 6, using the term "expandable member" approximately 70 times).) Dr. Aklog also admitted at deposition that Claim 1 recites "additional functional language" supporting this term. (Ex. D (Aklog Tr.) at 107:17-20; Ex. G (Aklog Rpt.) at ¶ at 82.) "Structure may [] be provided by describing the claim limitation's operation," and the '629 patent does exactly this—"expandable member" is not some free-floating term, but instead exists within the context of an ultrasound apparatus that functions to modulate renal nerves. *Enplas Display Device Corp. v. Seoul Semiconductor Co., Ltd.*, No. 13-cv-05038 NC, 2015 WL 1062676, at *12 (N.D. Cal. Mar. 11, 2015) (quoting *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1300 (Fed. Cir. 2014)). "[T]he mere fact that the disputed limitations incorporate functional language does not automatically convert the words into means for performing such functions." *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1008 (Fed. Cir. 2018).

Because a POSA would understand "expandable member" in the context of the '629 patent as having a sufficiently definite structure with an understood scope, the Court should not apply § 112(6) and should instead assign the term its plain and ordinary meaning.

F. "positioned on a shaft of the catheter" (Claim 1)

Medtronic's Proposed Construction	Recor's Proposed Construction
Plain and ordinary meaning / no construction necessary.	In direct contact with a shaft of the catheter without any intervening structure.

Recor's proposed construction of "positioned on a shaft of the catheter" would improperly narrow the term such that the claimed transducer must be *in direct contact with* the shaft of the catheter *without any intervening structure*. But a POSA would recognize the '629 patent uses the term according to the plain meaning of "on a shaft," and nothing in the intrinsic record supports Recor's narrowing construction. (*See* Ex. C (van der Weide Rpt.) at ¶ 82.)

Starting with the claim itself, claim 1 recites "the ultrasound transducer is positioned on a shaft of the catheter and within the expandable member." (Ex. A at Claim 1.) Neither this language nor any other part of the claim requires that the transducer be in direct contact with the catheter without intervening structure. *See Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, No. CV 19-149 (MN), 2019 WL 2521305, at *6 (D. Del. June 6, 2019) (finding a POSA would not understand a the term to require direct contact where the claim "does not use language indicating that direct contact is required.").

The '629 specification also does not establish any special meaning of the term: it describes an embodiment with "ultrasound transducers 364 positioned along the shaft of the catheter within an inflatable balloon 366," as depicted in Figure 12. (Ex. A at FIG. 12, 14:31-34.) As Dr. van der Weide explained, a POSA would know there are multiple ways a transducer can be "positioned on a shaft of the catheter" and would not read the specification to require a specific one. (Ex. C (van der Weide Rpt.) at ¶ 84.) Moreover, "although the specification often describes very specific embodiments of the invention, [the Federal Circuit has] repeatedly warned against confining the claims to those embodiments." *Phillips*, 415 F.3d at 1323.

This claim term was at issue during both the prosecution of the '629 patent and the IPR proceedings, and in both cases Medtronic's positions were consistent with the plain meaning.

(*See* Ex. C (van der Weide Rpt.) at ¶ 85.) To the extent Recor argues prosecution history disclaimer applies it must show a disclaimer "both clear and unmistakable to one of ordinary skill in the art." *See Tech. Properties Ltd. LLC*, 849 F.3d at 1357 (citation omitted). To Dr. van der Weide—a qualified POSA—there is nothing in the original prosecution history or IPR history that "warrants a narrowing reading of the term as Recor proposes." (Ex. C (van der Weide Rpt.) at ¶ 91.) And Recor's expert provides no opinion to the contrary.

During prosecution, when the pending claims did not require that the transducer be positioned on a shaft of the catheter, the examiner cited U.S. Patent No. 6,254,598 to Edwards ("Edwards"), noting that it teaches one or more ultrasound transducers "positioned along the catheter" and that "may be attached directly to the inflatable balloon." (Ex. K ('629 Patent File History, 8/29/2013 Office Action) at p. 5).) Medtronic then amended the claim language to recite that the ultrasound transducer is "positioned on a shaft of the catheter." (Ex. L ('629 Patent File History, 10/31/2013 Amendment) at p. 2.) This amendment overcame Edwards because it clarified that a transducer only *attached to an expandable balloon* cannot be "positioned on a shaft of the catheter." Nowhere, though, did Medtronic disclaim *any* transducer that was not in direct contact with a shaft of the catheter. *See Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1330 (Fed. Cir. 2003) (holding there was no "unmistakable" disclaimer of claim scope to justify a narrowing departure from a term's plain meaning based on an amendment during prosecution where there was a plausible rationale for the amendment unrelated to the proposed narrowing).

This term was also at issue in the IPR, where Recor asserted U.S. Patent No. 6,669,655 ("Acker") as prior art. In its Institution Decision, the PTAB found that Recor sufficiently showed that Acker's arrangement—which includes a multi-layer transducer on a rigid base that sits between the transducer and the catheter—met the "positioned on a shaft of the catheter" limitation. (Ex. M (IPR Institution Decision) at pp. 33-34.) While Medtronic contended that Acker does not teach this limitation, it took no position as to the general meaning or scope of "positioned on a shaft of the catheter." Rather, Medtronic argued that Acker's specific arrangement in which the "transducer is positioned *outside* of the shaft" does not meet the

"positioned *on* a shaft of the catheter" limitation. (Ex. N (IPR Preliminary Response) at pp. 65-66 (emphasis added).) This is not an "unmistakable" disclaimer of *any* transducer that is not in direct contact with the shaft of the catheter without any intervening structure. *See Omega Eng'g*, 334 F.3d at 1330. More importantly, the PTAB explicitly rejected Medtronic's position on this point. (Ex. M at pp. 33-34.) Where, as here, a patentee's "statements were clearly and expressly rejected by the Patent Office," there can be no disclaimer. *See Galderma Lab'ys, L.P. v. Amneal Pharms. LLC*, 806 F. App'x 1007, 1010–11 (Fed. Cir. 2020). In view of the PTAB's finding, Recor's proposed construction directly contravenes the prosecution history. This Court should decline to construe this term and instead afford it its plain and ordinary meaning.

VI. EVALUATION OF DISPUTED TERMS IN THE '085 PATENT

A. "deliver the energy, via the at least one neuromodulation element, to the neural fibers to reduce sympathetic nerve activity" (Claim 1) / "deliver, via the at least one neuromodulation element, energy sufficient to ablate renal neural fibers adjacent to the renal vessel" (Claim 12)

Medtronic's Proposed Construction	Recor's Proposed Construction
Plain and ordinary meaning / no construction necessary.	The neuromodulation element delivers [energy sufficient to ablate renal neural fibers to the neural fibers to reduce sympathetic nerve activity] (cl 1) / [energy sufficient to ablate renal neural fibers adjacent to the renal vessel] (cl 12)

The parties' dispute regarding this term turns on Recor's attempt to read into the patent claims an additional requirement that the neuromodulation element deliver the energy. Recor's construction is contrary to the express claim language, and should not be adopted by the Court.

Claim 1 of the '085 patent recites a generator that is "configured to . . . deliver the energy, via the at least one neuromodulation element, to the neural fibers to reduce sympathetic nerve activity," and Claim 12 recites "causing a generator to generate and deliver, via the at least one neuromodulation element, energy sufficient to ablate renal neural fibers adjacent to the renal vessel." These terms have a plain and ordinary meaning to a POSA, and there is nothing that requires changing the language or assigning the terms any other special meaning.

Recor's proposed construction, however, actually *changes* the meaning of the claims, which expressly say that the *generator* is configured to deliver the energy. Recor's proposal

omits the role of the generator and assigns the energy delivery to only the neuromodulation element. While the neuromodulation element contributes to energy delivery (as reflected in Medtronic's proposal for that term), the claim itself says it is the generator that delivers the energy via the neuromodulation element. There is no reason to depart from the actual language of the claim. Additionally, for claim 1, Recor's proposal would replace the words "the energy" with "energy sufficient to ablate renal neural fibers." While "the energy" refers via antecedent basis to the "energy" referenced previously in the claim, there is no reason to replace the words of the claim. Recor's proposed construction renders the language unwieldly and more likely to confuse a jury, rather than less confusing as claim construction is intended to do. *See, e.g., Lone Star Tech. Innovations, LLC v. Asustek Comp. Inc.*, No. 6:19-CV-00059-RWS, 2020 WL 6811484, at *20 (E.D. Tex. July 31, 2020) (rejecting a construction where it "renders the claim even more unwieldy, increasing the likelihood of jury confusion").

This claim term is properly given its plain and ordinary meaning and should not be construed as Recor proposes.

B. "neuromodulation element" (Claims 1, 12)

Medtronic's Proposed Construction	Recor's Proposed Construction
"element that delivers energy for neuromodulation"	Means-plus-function under 35 U.S.C. § 112 ¶ 6 (pre-AIA). **Functions**: (1) "neuromodulation" and (2) ["deliver the energy … to the neural fibers to reduce sympathetic nerve activity in the neural fibers"] (cl. 1) / ["deliver … energy sufficient to ablate renal neural fibers adjacent the renal vessel] (cl. 12) **Structure**: a concave ultrasound transducer configured to focus the ultrasound on a point as shown in Fig. 15.

The construction of "neuromodulation element" is of critical importance to this case. Recor improperly proposes narrowing its meaning to a single example embodiment in the specification, specifically a "concave ultrasound transducer configured to focus the ultrasound on a point," excluding the many other disclosed embodiments and disregarding the claim language itself, including that of dependent claims 3-5. Nothing in the intrinsic or extrinsic evidence supports Recor's narrow and litigation-inspired construction, and the Court should

construe this term according to its plain and ordinary meaning, as an "element that delivers energy for neuromodulation."

This term appears in claims 1 and 12. As the claims say, it is the "neuromodulation element" through which energy is delivered from a generator to the target nerves to carry out neuromodulation: "a generator … configured to . . . deliver the energy, *via the at least one neuromodulation element*, to the neural fibers." Neither the neuromodulation element nor the energy delivered through it is limited in the ways proposed by Recor.

First, the independent claims of the '085 patent are not limited to any specific type of energy (i.e., ultrasound, as Recor's construction would do). Rather, the specification teaches that ablation may be achieved through the delivery of "electromagnetic energy, radiofrequency, ultrasound (including high-intensity focused ultrasound), microwave, light energy (including laser, infrared and near-infrared)[,] etc., to the target neural fibers." (Ex. B at 4:53-56.) This is confirmed by the dependent claims which specify that the neuromodulation element can be an "electrode" (claims 3, 14), an "ultrasound transducer" (claims 4, 15), and a "microwave transducer" (claims 5, 17), each requiring a different type of energy. This narrowing in the dependent claims implicates the doctrine of claim differentiation, wherein "independent claim[s] should not be construed as requiring a limitation added by a dependent claim." *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006). As a result, because these dependent claims limit themselves to certain types of energy, it is improper to restrict the independent claims to any given one.

Next, the specification (as well as the dependent claims listed above) describes several types of neuromodulation elements. This is not surprising as different elements would be required for providing the different types of energy contemplated in the specification. For example, "electrodes" (Ex. B at 10:23-25), "thermoelectric or Peltier elements" (*id.* at 22:42-44), and "ultrasound transducers" (*id.* at 24:18-21). A POSA would therefore understand "neuromodulation element" refers to any number of different elements, and would recognize these examples as consistent with its plain and ordinary meaning. (Ex. C (van der Weide Rpt.) at ¶ 105.) Because the term does not require any special construction to align with the

understanding of a POSA, or to capture the example embodiments of the specification, the term is properly given its ordinary meaning.

Nevertheless, ignoring the intrinsic record and Federal Circuit authority, Recor argues that "neuromodulation element" is a means-plus-function term and should be limited to "concave ultrasound transducers configured to focus the ultrasound on a point as shown in Fig. 15." Through its proposal, Recor is really asking the Court to limit Medtronic's claims not just to ultrasound but to *focused* ultrasound—i.e., the example shown in Fig. 15—and to exclude *unfocused* ultrasound and all other types of energy. Recor's construction also improperly excludes the wider scope of neuromodulation elements plainly contemplated by the specification and ignores the presumption *against* applying § 112(6). Recor's excessively narrow construction—which is improperly motivated by its noninfringement arguments—cannot succeed as it ignores the '085 patent's broader teaching of using a variety of energy modalities and also ignores *specific* embodiments of "neuromodulation element[s]" using other forms of energy.

Moreover, because this claim term does not use the word "means" there is a presumption against applying § 112(6). *See Inventio AG v. Thyssenkrupp Elevator Americas Corp.*, 649 F.3d 1350 (Fed. Cir. 2021) at 1356 ("[W]here, as here, the claim language does not recite the term 'means,' we presume that the limitation does not invoke § 112, ¶ 6."). Recor cannot meet its burden of overcoming this presumption "by a preponderance of the evidence," because a POSA would recognize "neuromodulation element" as a structural element. *See Dyfan*, 28 F.4th at 1370. This is particularly true in view of the surrounding claim elements reciting that the "neuromodulation element" is carried by "a distal portion of [a] catheter" in a patient's renal nerve, able to deliver "energy sufficient to ablate renal neural fibers," and is "spaced radially inward" from the "expandable positioning element." (Ex. B at 33:50-34:9.) As Dr. van der Weide testified, a POSA would recognize "neuromodulation element" as a class of objects that can deliver energy for renal nerve ablation and "having underlying similarities and characteristics such that they would understand the scope of the term." (Ex. C (van der Wide Rpt.) at ¶ 107.) As here, § 112(6) should not apply where "the claim term is used in common

parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their function." *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1359-60 (Fed. Cir. 2004).

Even if § 112(6) applies, Recor's construction ignores structures plainly disclosed by the '085 patent. Recor fixates on Figure 15, but this ignores that Figures 5-14 also disclose "neuromodulation elements" for ablating renal nerves, including "neuromodulation elements" other than ultrasound transducers. (*See* Ex. B at 2:49-3:37.) "[I]t is incorrect to construe claims contrary to the specification, and it is incorrect to construe terms in means-plus-function form as disembodied from the structure in the specification." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1361 (Fed. Cir. 1998). Recor proposes to do exactly that, and the Court should reject its proposal.

C. "generator" (Claims 1, 12)

Medtronic's Proposed Construction	Recor's Proposed Construction
Plain and ordinary meaning / no construction necessary.	Indefinite. Or means-plus-function under 35 U.S.C. § 112 ¶ 6 (pre-AIA). **Functions**: (1) generate energy sufficient to ablate renal neural fibers adjacent a renal blood vessel of the patient and (2) deliver the energy sufficient to ablate the renal neural fibers to the neuromodulation element. **Structure** Indefinite or (a) power generator, (b) a cable, (c) a temperature sensor, and (d) a controller/processor operating in accordance with the algorithm shown in steps 1602, 1604, and 1606 in Figure 16.

In support of its proposal for the term "generator," Recor jumps through analytical hoops—first saying this well-known term would not be understood by one of skill in the art and is indefinite, and then adding multiple components to the generator without any support in the claims or specification. Again here, Recor's motivation is clear: to severely narrow the claims such that Recor avoids infringement, or with this term, to invalidate the '085 patent. There is no basis, in law or fact, for either result.

The Court should assign "generator" its plain and ordinary meaning because a POSA—someone with advanced expertise in the technical field—would readily understand what is meant by a "generator" in the context of the '085 patent. The patent's specification teaches:

> [A] field generator 110 can generate electrical, radiofrequency, ultrasonic (including high intensity focused ultrasound), microwave, laser or other types of signals with desired parameters sufficient to thermally or otherwise induce renal neuromodulation in target neural fibers.

(Ex. B at 7:33-41.) As Dr. van der Weide explained, a POSA "would understand that a generator, as the word is commonly used according to its plain and ordinary meaning, captures these examples without requiring a special construction." (Ex. C (van der Weide Rpt.) at ¶ 112.) Moreover, a POSA "would further recognize that 'generate energy' and 'deliver [] energy' are common and well understood functions of a generator, as the term is commonly understood." (*Id.*) As such, no special construction is required to capture these examples and functions, and a POSA would accord the term its plain and ordinary meaning.

Recor's proposal, on the other hand, disregards the knowledge of a POSA.[8] Instead, at least as Medtronic understands it, Recor first proposes that "generator" should be interpreted as a means-plus-function term, and then argues that, because the claims do not convey sufficient structure of that means, the term is properly limited to the specification. From there, Recor argues that the specification identifies a number of components of a generator, and that because the specification is also insufficiently specific as to one of those components, the term is indefinite. (*See* Ex. G (Aklog Rpt.) at ¶ 105.) Because the term generator is found in both independent claims, Recor argues that the entire '085 patent is therefore invalid.

Recor's analysis is strained at every leap. As an initial matter, because the "generator" term lacks the word "means," there is a presumption *against* applying § 112(6). *See Dyfan*, F.4th at 1370. There is nothing in the '085 patent's claim language, specification, or file history that overcomes this presumption. Indeed, a POSA would understand "generator" as having a definite structure with an understood scope simply by reading the claims in the context of the

[8] It is difficult to believe Recor and its expert would not understand the structure associated with a generator of a neuromodulation system when its own accused product includes one.

patent. And Recor's expert agrees: "the term 'generator' by itself connotes some structure, a POSA would understand the structure to be a general-purpose generator that can generate energy or signals." (Ex. G (Aklog Rpt.) at ¶ 106.) This alone ends the inquiry and supports a plain and ordinary meaning.

Recor nevertheless then looks to the specification and contends that the corresponding structure requires a host of additional components—including a cable, a temperature sensor, and a controller/processor. (*Id*. at ¶ 113.) Recor's expert next concludes that the specification does not sufficiently describe the structure of the temperature sensor. (*See id.* at ¶¶ 113-126.) So somehow, according to Recor, the specification does not sufficiently describe the corresponding structure of the "generator" to perform the claimed functions, rendering "generator" either indefinite (and the '085 patent invalid) or the claims limited to a very specific embodiment.

First, nowhere do the claims of the '085 patent require a temperature sensor.[9] A "temperature sensor" *only* appears in the specification, and it is improper to "import limitations from the specification into the claims." *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005). Moreover, the '085 patent teaches that although the invention "*can* include a temperature sensor," the invention *could also include* "an impedance sensor, an ultrasound sensor, and/or other types of sensors." (Ex. B at 8:14-18.) Recor's indefiniteness argument fails because Recor only gets to this result by answering the wrong question. The issue is not whether a POSA would understand the structure of a temperature sensor—an unclaimed component that is only relevant because Recor introduces it in its construction—but rather whether a POSA would understand the structure of the claimed generator. And, as explained above, they decidedly would.

Ultimately, Recor strains to apply § 112(6) to the term "generator" in an attempt to reach either patent invalidity or a narrow construction to support its non-infringement positions. Both lack legal and factual support and should be rejected.

[9] It is no coincidence Recor alleges its accused product does not include a temperature sensor, but "claims may not be construed with reference to the accused device." *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1330-31 (Fed. Cir. 2006) (citations omitted).

D. "expandable positioning element" (Claims 1, 12)

Medtronic's Proposed Construction	Recor's Proposed Construction
Plain and ordinary meaning / no construction necessary.	Means-plus-function under 35 U.S.C. § 112 ¶ 6 (pre-AIA). **Function**: (1) expand by being "transformable from a low profile delivery configuration to an expanded configuration," (2) position the device within the blood vessel by, when "in the expanded configuration, [placing] the at least one neuromodulation element … radially inward from an outer diameter of the expandable positioning element," and (3) "receive a cooling fluid configured to remove heat from within the expandable positioning element." **Structure**: an inflatable balloon.

For the reasons discussed above for "expandable member," "expandable positioning element" does not require construction, and the Court should assign it its plain and ordinary meaning because a POSA would understand its scope and structure in the context of the claims. Nonetheless, Recor yet again contends that this claim term should be viewed as a means-plus-function term and limited to a single embodiment.

As above, there is a presumption that § 112(6) does not apply because the "expandable positioning element" term lacks the word "means," and Recor bears the burden of rebutting this presumption. *See Dyfan*, F.4th at 1370. Recor cannot do so here because, in the context of the '085 patent, the term has sufficiently definite structure. Claims 1 and 12 of the '085 patent specify that the "expandable positioning element" is "carried by a distal region of the catheter," is configured to vary between a "low profile delivery configuration [and] an expanded configuration," and is able to have a "neuromodulation element [] spaced radially inward from [its] outer diameter." (Ex. B at 33:61-34:9.) A POSA would recognize these requirements provide information about the structure of the "expandable positioning element" such that it is not just a functional term. (*See* Ex. C (van der Weide Rpt.) at ¶ 122.) For these reasons, the limiting application of § 112(6) is not warranted.

Recor's expert's testimony confirms this conclusion. As with "expandable member," Recor's expert admitted that the remainder of Claim 1 recites functions that additionally limit

the "expandable positioning element" term. (*See* Ex. D (Aklog Tr.) at 114:14-19, 115:10-116:12; Ex. G (Aklog Rpt.) at ¶ at 90.) Such "functional language does not automatically convert the words into [§ 112(6)]," *Zeroclick*, 891 F.3d at 1008, and instead, "structure may [] be provided by describing the claim limitation's operation." *Apple*, 757 F.3d at 1299. Moreover, Recor's expert also admitted that the rest of Claim 1 "provides additional detail about how the expandable positioning element relates to other claim elements." (Ex. G (Aklog Rpt.) at ¶ 90.) The relationship between different portions of an invention provides structure. *See, e.g.*, *Boston Sci. Corp. v. Cook Grp. Inc.*, No. 15-980-LPS-CJB, 2017 WL 3977256, at *3 (D. Del. Sept. 11, 2017) (construing "opening element" as *not* means-plus-function and noting that "other claim language[] [] describes how the opening element structurally relates to other portions of the claimed device").

Because a POSA would understand "expandable positioning element" in the context of the '085 patent as having a sufficiently definite structure with an understood scope, the Court should not apply § 112(6) and should instead assign the term its plain and ordinary meaning.

Even if the Court applies § 112(6) to "expandable positioning element," Recor's proposed structure is overly narrow. Recor proposes that only "an inflatable balloon" is the corresponding structure, but the '085 patent teaches that it can be much more than that. Specifically, the '085 patent teaches that the positioning element "can include, for example, an inflatable balloon *or an expandable basket or cage*." (Ex. B at 21:18-21 (emphasis added).) Similarly, it "can be a balloon, *an expandable wire basket, other mechanical expanders, or another suitable device*." (*Id.* at 10:16-18 (emphasis added).) As a result, *even if* the Court applies § 112(6) to "expandable positioning element," Recor's proposed construction unjustifiably excludes structures that the '085 patent directly ties to "expandable positioning element" and should therefore be rejected.

VII. CONCLUSION

Medtronic's proposed constructions of the disputed claim terms represent the plain and ordinary meanings to one of skill in the art and should be adopted.

Dated: July 26, 2024

Respectfully submitted,

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